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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,516	07/21/2002	Berhard Peter Harald Schaffar	RDID02002US	6356

7590

01/14/2004

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EXAMINER
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HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/031,516	SCHAFFAR, BERHARD PETER HARALD	
	<b>Examiner</b>	<b>Art Unit</b>	
	Susan Hanley	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 July 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-22 is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### ***Specification***

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites "matrix inclusion". It is unclear what the meaning of this term is.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Surareungchai et al.

Surareungchai et al. teach the immobilization of glucose oxidase (GO) on an electrode by contacting the electrode with an aqueous solution of GO and 1,3-diaminobenzene. This mixture polymerized into a film on the electrode. This disclosure meets the limitation that the enzyme is combined with a surface-active substance. A surface-active substance affect the surface tension of a composition. The

polymerization of the enzyme-containing solution will inherently cause a change in the surface tension of the solution. The coated electrode was then placed in a buffered solution containing invertase, mutarotase, BSA and glutaraldehyde. The glutaraldehyde chemically cross linked the enzymes onto the electrode (p. 9, top paragraph, right column).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okahata et al. in view of Sirkir et al, Armstrong et al. and Cozzette et al. (US 5,837,454).

Okahata et al. teach the immobilization of glucose oxidase onto an electrode by combining GO and an amphiphile in a chloroform solution and then coating an electrode with said solution and allowing the electrode to dry (p. 66, middle paragraph). The amphiphile can be a non-ionic tenside (Table I). Okahata further teaches that different enzymes can be added in double or triple decker-type films on top of the GO-immobilized layer (p. 71).

Okahata et al. do not teach that GO can be deposited with a surfactant onto an electrode via an aqueous solution, that the subsequent layers of enzymes can be cross-linked, the employment of a cover membrane or the use of Tween as a surfactant.

Armstrong et al disclose the immobilization of aqueous solutions of enzymes on an electrode followed by drying (p. 2626, right column, middle paragraph). Armstrong et al. teach that the use of an aqueous solution of enzyme and surfactant is an equal alternative to using an organic solution of enzyme and surfactant. Successive layers of enzymes can be immobilized by chemical immobilization (p. 2639, left column).

Sirkir et al. teach the immobilization of successive layers of GO and lactate enzyme onto electrodes through deposition of anionic self-assembled monolayers. The multiplayer structure is chemically cross-linked by glutaraldehyde to stabilize the structure (abstract).

Cozzette et al disclose that non-ionic surfactant such as Triton or Tween promote plazarization of matrices of enzymes absorbed onto electrodes (col. 32, line 30-40). Cozzette further disclose that the electrode can be covered by a photoresist cap for protection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an aqueous solution of enzyme and surfactant to an electrode wherein the surfactant is Tween, to cross link the subsequent layers of enzyme and to cover the electrode with a membrane. Armstrong et al. disclose that the use of organic and aqueous solution for casting enzymes and surfactants is well known in the art and that the choice is well within the purview of the ordinary artisan. The ordinary artisan would have been motivated to cross link subsequent layers because cross linking is known to strengthen multi-layer enzyme electrodes. Tween is well known as a detergent, and Cozzette points out that the choice of detergent for enzyme

casting is well within the purview of the ordinary artisan. Further the ordinary artisan would have been motivated to add a membrane cap to the electrode to protect the multi-layered enzymes on the electrode.

***Allowable Subject Matter***

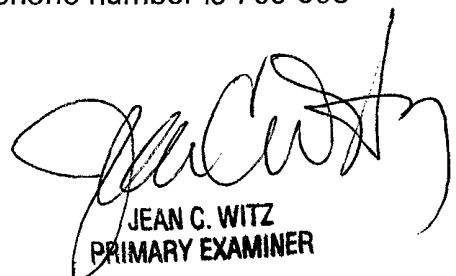
The following is a statement of reasons for the indication of allowable subject matter: A biosensor comprising separate layers of creatinase, creatininase and sarcosine oxidase, wherein the first layer of enzyme is contacts the electrode in the presence of surfactant and subsequent layers are chemical cross linked is neither anticipated or obvious over the prior art.

Claims 19-22 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
JEAN C. WITZ  
PRIMARY EXAMINER